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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,725	01/27/2006	Hideki Tanji	10921.0296USWO	9962
52835	7590	01/22/2009		
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER TURK, NEIL N	
			ART UNIT 1797	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,725	<b>Applicant(s)</b> TANJI, HIDEKI	
	<b>Examiner</b> NEIL TURK	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Remarks***

This Office Action fully acknowledges Applicant's remarks made on October 14<sup>th</sup>, 2008.

Claims 1-13 are pending. Claims 14-18 have been cancelled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the amended recitation in claim 1, "...on a predetermined relationship between variations of response and variations of wavelength with respect to a reference board whose response varies continuously as the wavelength of light irradiated onto the reference board varies." Likewise, the amended recitation of claim 6 of, "...a storage for storing a relationship between variations of response and variations of wavelength with respect to a reference board whose response varies continuously as the wavelength of light irradiated onto the reference board varies" is unclear. The claims do not recite a step of applying differing (varying) wavelengths as irradiating light and the light irradiator of the device is not recited as providing differing (varying) wavelengths for irradiating the reaction system and reference board. The claims have not made clear that the irradiating is done at multiple wavelengths (nor that the light source provides such a spectrum or multiple wavelengths). The claims have not made clear that the measuring is done at multiple wavelengths. The claims have

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also not made clear what causes fluctuations (variations of response) of measurement wavelength. Claims 1-13 are indefinite to providing for such a relationship between variations of response and variations of wavelength with respect to the reference board, and such a relationship does not have basis in the claims for use in the calculation step or for use with the calculator. Clarification is required.

**Claim 1** recites the limitation "the reference board". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Matzinger (5,780,304).

Matzinger discloses a method and apparatus for analyte detection having an on-strip standard. Matzinger discloses that the invention relates to a test device and method for optically measuring the concentration of glucose in whole blood (lines 8-12, col. 1). Matzinger discloses a test strip that has a reaction zone (with color-producing reagent), which varies in reflectance as a function of the quantity of analyte present, and a standard zone that is positioned so as to lead the

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reaction zone as the strip is inserted into a reading apparatus. Matzinger discloses that the apparatus has optical means for sequentially determining the reflectance value of the standard zone and for determining the reflectance value of the reaction zone after the strip has been inserted. The apparatus further includes means for calculating the presence and/or quantity of the analyte as a function of the standard zone and reaction zone reflectance (abstract; lines 26-60, col. 4; lines 61-67, col. 8; lines 1-31, col. 9). Matzinger discloses the apparatus 12 is provided with a power switch 20 for activating the apparatus and the optics block 32 is affixed to the apparatus and operable to direct light through aperture 30 in rapid bursts, "chops", for a period of time each time it is activated (lines 50-67, col. 5; lines 19-35, col. 6, figs. 1-3). Matzinger discloses that the standard zone 60 provides a calibrated standard reflectance value against which the reflectance of the color-developed reaction zone may be measured so as to allow computation and reporting of the presence or quantity of the analyte (lines 40-67, col. 9; lines 1-21, col. 10; lines 6-28, col. 11; figs. 1, 4, and 6). Matzinger also discloses that the reflectance of the surface presented to the optics is measured at all the various positions and multiple readings are taken at each position in spaced periods of time (lines 30-67, col. 11, figs. 7-11). Matzinger further discloses that the apparatus views the gray target and read a value for its reflectance at each LED wavelength and compare the values to the factory stored values for the gray reading. If there is a difference between the stored readings and the actual readings an adjustment is made (lines 36-50, col. 6; lines 5-67, col. 13). Matzinger discloses further calibration measures and checks throughout column 14. Matzinger also discloses that the microprocessor employs a look-up table to provide proper coefficients for calibration of the specific test strip employed in the apparatus to correct K/S ratio (lines 1-60, col. 15). Examiner interprets the function of the microprocessor

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to check and compare the gray readings against factory-stored values for adjustments to correspond to the selector and calculation corrections as claimed.

### ***Response to Arguments***

Applicant's arguments filed October 14th, 2008 have been fully considered but they are not persuasive.

**With regards to claims 1-13** rejected under 35 USC 102(b) as being anticipated by Matzinger et al. (5,780,304), Applicant traverses the rejection.

Applicant argues that in Matzinger adjustment is made so that each of different measuring apparatuses provides a proper quantity of light energy of each LED designed to emit at a fixed wavelength of 660nm or 940nm. Applicant argues that the standard zone 60 only provides a higher reflectance than a reaction zone, and wavelength dependence of the standard zone is not used for measurement correction. Applicant argues that Matzinger does not disclose or suggest using a predetermined relationship between variations of response and variations of wavelength with respect to a reference board, whose response varies continuously as the wavelength of light irradiated onto the reference board varies, and thereby, Matzinger cannot disclose the calculation step as claimed. Examiner argues that Applicant's arguments are not commensurate in scope with the claims. The claims do not recite a step of applying differing (varying) wavelengths as irradiating light and the light irradiator of the device is not recited as providing differing (varying) wavelengths for irradiating the reaction system and reference board. The claims have not made clear that the irradiating is done at multiple wavelengths (nor that the light source provides such a spectrum or multiple wavelengths). The claims have not

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made clear that the measuring is done at multiple wavelengths. The claims have also not made clear what causes fluctuations (variations of response) of measurement wavelength. Claim 1 is indefinite to providing for such a relationship between variations of response and variations of wavelength with respect to the reference board, and such a relationship is indefinitely recited and does not have basis in the claims for use in the calculation step. Examiner argues that thereby Matzinger discloses such a calculating step, as the presence and/or quantity of the analyte is calculated as a function of both the standard zone reflectance (1<sup>st</sup> detection result; which provides a calibrated standard reference value) and reaction zone reflectance (2nd detection result) (abstract; line 40-67, col. 9; line 1-60, col. 15; col.9-15, figs. 4-11).

With respect to the device of claims 6-13, Applicant argues that Matzinger does not disclose the features. Applicant applies similar arguments as those presented above with respect to the method of claims 1-5. Applicant's arguments are not commensurate in scope with the claims. As discussed above, Applicant does not require different (varying) wavelengths of light to irradiate the reference board and the calculation step is indefinitely recited. Further, Applicant argues that Matzinger does not disclose a storage for storing a relationship between variations of response and variations of wavelength with respect to a reference board whose response varies continuously as the wavelength of light irradiated onto the reference board varies. Examiner asserts that Applicant has recited a storage with functional capabilities, and the microprocessor, which has a storage, is capable of such a functionality. Applicant further argues that Matzinger cannot disclose or suggest a calculator connected to the detecting unit and the storage for calculating a concentration of a component based on the relationship and the first and second responses. Examiner argues that Claim 6 is indefinite to providing for such relationship between

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variations of response and variations of wavelength with respect to the reference board, and such a relationship does not have basis in the claims for use in the calculation. Thereby, as discussed above, the device of Matzinger, as shown in figure 6 and 7-11 (calculator and storage said to be within the microprocessor), for example, provides for a calculator as claimed, as such a predetermined relationship is indefinitely recited and does not have basis in the claims. Claims 1-13 are maintained rejected as discussed above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797